Eur J Vasc Endovasc Surg (2008) **36**, 253–257

CAROTID MASTERCLASS

When Does the 'Learning Curve' of Innovative Interventions Become Questionable Practice?☆

P. Healey*, J. Samanta

The Department of Law, De Montfort University, Leicester, UK

Submitted 23 May 2008; accepted 23 May 2008
Available online 30 June 2008

KEYWORDS
Innovative practice;
Learning curve;
Informed consent;
Clinical negligence;
Clinical equipoise;
Regulation

Abstract Demand for less invasive surgical intervention has increased in recent years resulting in surgeons occasionally being pressurised into adopting new techniques before evidence of safety and efficacy has been established. Unlike pharmaceutical research, most innovative surgical procedures enter surgical practice without regulatory oversight. This anomaly was recently highlighted in the 'Bristol Report' resulting in a recommendation that unproven therapies or surgical techniques be subjected to ethical overview or independent oversight.

When a novel technique is introduced, the surgeon will find himself/herself gaining proficiency and experience on suitable patients. Hence the surgeon embarks on a 'learning curve'. A learning curve can be defined as a graphic representation showing the relationship between experience with a procedure and outcome. Studies demonstrate that learning curves generally 'flatten out' as experience increases, resulting in fewer complications and less of a need to convert to the standard procedure.

In addition to lack of regulatory oversight, it is this learning curve that gives rise to many ethical and legal dilemmas. This paper considers the ethical issues relating to a surgeon's candour and clinical equipoise, the legal standard of care in a negligence action and the ethical and legal implications regarding risk disclosure during informed consent. The paper concludes by considering a more patient centred approach where new and innovative therapies are being considered in order to ensure good medical practice and avoid litigation for allegations of negligence or breach of human rights.

Introduction

The learning curve where beginners hone their skills prior to passing on the benefit to others is a necessary and, to a large extent, unavoidable aspect of becoming a competent and skilled practitioner. Advancements such as computer

☆ One of a series of articles edited by Prof. A. Ross Naylor, Leicester, UK.

* Corresponding author. P. Healey, Senior Lecturer in Law, Department of Law, De Montfort University, Elfed Thomas Building, The Gateway, Leicester LE1 9BH, UK. Tel.: +44 116 2577225.
E-mail address: phealey@dmu.ac.uk (P. Healey).

1078-5884/$34
doi:10.1016/j.ejvs.2008.05.006

assisted role play with innovations such as avatars and 'Second Life' might be usefully employed to help clinicians gain proficiency in skills. For surgeons, workshops (often funded by industry) are established in order to train and develop skills in using innovative surgical devices/techniques. Operating on cadavers and animals may also offer useful opportunities to practice surgical technique. The final test, however, is to intervene upon a patient. This is a situation where there is no entirely satisfactory alternative, particularly where new and innovative surgical/interventional techniques are being considered.

This paper considers the ethical and legal dilemmas that lie at the heart of the learning curve associated with innovative surgery, particularly for otherwise experienced clinicians. Candour, effective communication and informed consent are central to this discussion, and are of increasing importance as well as relevance for surgeons. Entry into clinical research studies requires a centre to qualify as one of excellence prior to participation: a situation usually proved by the successful completion of a qualifying number of procedures. We will confine ourselves to consideration of competent adults and propose a more patient-centred approach to consent as well as rapid dissemination of early findings in an endeavour to maximise benefits and reduce potential harm to patients. The law stated is as applied in England and Wales.

Innovation in Surgical Practice

Innovation and creativity has preceded most major advancements in surgery and, without doubt, retains a fundamental role in the continual and sustained development of clinical practice. Major surgical (interventional) advancements have in the main been acquired by incremental and sustained modification of treatment. The drive to continually improve and enhance quality outcomes places surgical innovation as pivotal to clinical progress, a position which might potentially present risks to patients and professional reputations alike.

In certain circumstances, evidence may suggest that the use of a novel technique is reasonably safe, provided safety and durability markers following 'bench testing' animal data are available. There may even be some evidence from research on humans that has emanated from countries where ethical and legal restraints are possibly less stringent. However, surgeons can also adopt new technologies into their practice, even when there is little in the way of evidence to support the efficacy of such innovation.

The rate of advancement in surgical practice together with rapid dissemination by internet and the media has meant that surgeons are very soon aware of the latest innovations. This may encourage surgeons (sometimes at the behest of patients) to demand access to innovative procedures before they have been validated. In the United States the American College of Surgeons has stated that it is ''essential that the value and safety of a new procedure is established before it is widely used on patients.''[1] The learning curve of innovative practice creates ethical and legal tensions. Clinicians have a professional obligation to continually develop and improve their expertise, which to some degree can be met by the discretion to innovate. A system that over regulates could stifle surgical advancement and fetter creativity aimed at improving patient care.

Innovative Intervention or Research?

Clinical interventions have traditionally been classified as: established treatment; innovative therapy, or research procedures.[2] The aim of medical treatment is to care for each patient in his/her own best interests, whereas medical research is undertaken in order to produce new information and knowledge for the collective benefit of future recipients of care. The aim of research is not primarily for the benefit of an individual patient, although incidental benefits may, of course, be acquired. Research has therefore been distinguished from conventional therapy on the grounds of the clinician's intent.[3]

To some extent, advances in surgical therapy represent a form of research, in that the outcome (which might be of therapeutic benefit to the individual patient) could arguably be of value to future patients as well as of educational benefit to the doctor concerned. The accurate conceptualisation of innovative therapy is, therefore, an essential precursor to its further analysis. In the UK, there is much greater regulation and oversight in animal experimentation than there is for evaluating innovative techniques in surgery. It would, therefore, seem unquestionable that therapeutic innovation ought to be subject to similar regulatory oversight as any other clinical research regime.

The lack of a clear distinction between research and innovation has (to some extent) constrained the ability of independent evaluation, regulation and continual monitoring.[4] As a result, certain procedures have entered mainstream practice without prior validation and regulatory oversight. Innovative therapy encompasses a wider range of activity than formal research activities. In the context of surgical practice minor modifications of procedure in circumstances where increased risk to patients is not expected will fall within the category of standard medical care, since by its nature clinical care must be adapted to suit individual patient need. In these circumstances the necessary modifications to care will be implied and incorporated under the umbrella of consent for the original procedure.

This situation is, however, fundamentally at variance from a planned surgical intervention where a new procedure that differs from an established one is to be undertaken. Whether such a practice might pose a greater risk to patients will, at this stage, be unclear. An innovation that is precipitated by a bespoke clinical need will be ethically justified and the consent process should ideally include specific reference to the experimental and possibly unique dimension of the procedure. Omission of this detail would undoubtedly violate a patient's right to self-determination and could be the catalyst for a subsequent legal or regulatory action.

The categorisation of therapeutic care, innovation and research is convenient and intellectually attractive. However, it obscures the reality that in some situations no clear line of demarcation exists between innovation and research. This distinction is critical. Whilst therapeutic care and ''tinkering at the edges'' is subject to professional

discretion, clinical research is a stringently regulated area. The point at which research ethical committee oversight is required remains nebulous.

Innovation as a Sentinel Standard of Care

Clinicians tend to introduce incremental modifications in light of experience and patient-centred care. The Bristol Report stated that it would be unacceptable for unproven therapies or surgical techniques to be undertaken without formal ethical overview or independent oversight. The Report states that patients have a right to be told, as part of the consent process, of the *experience that the doctor has had in that particular procedure*. This position is in congruence with common law. Since 1998, the remit of the National Institute for Health and Clinical Excellence includes the assessment and efficacy of innovative therapies. New pharmaceutical products are subject to research ethical committee approval, whereas equivalent ethical oversight of surgical innovation is not always the norm. New surgical techniques have traditionally been introduced into clinical care in an unregulated fashion, largely at the discretion of the surgeon concerned.[5] Indeed this is amply illustrated in the advancement of the 'laparoscopic revolution' which was introduced without any formal regulation or control.[6] Similarly, with Endovascular Aneurysm Repair (EVAR), the risk, cost and outcomes of this novel procedure were uncertain at the time of introduction and were quickly adopted, despite a lack of evidence regarding its safety and efficacy. Nowadays much of contemporary surgical advancement is driven by commercial enterprise, especially with regard to the introduction and development of new surgical devices. The importance of independent review, as recommended by the Bristol Inquiry is therefore heightened.[7]

Traditionally, clinical discretion has had wide latitude in the context of pioneering therapy.[8] Without doubt, however, innovatory enterprise must be subject to principled independent scrutiny. Ethical acceptability mandates that the potential benefits of an intervention outweigh any inherent risks of harm.[9] Harm in this context ought to be interpreted wider than physical harm and should encompass loss of trust or damage to the reputation of the medical profession.[10] Patients who agree to participate in research or innovative practice must always be treated in their best interests, and never as a means to an end. The principle of protecting human subjects must supersede the anticipated 'greater good' of clinical research.[11]

When new technology is introduced, a surgeon has to gain experience in using the technique. Often, the surgeon attends weekend workshops or enrols on short courses in an attempt to acquire the skills inherent in that procedure. It is arguable whether training such as this is sufficient. It has been argued that ''the presumption that new and technically demanding surgical skills can be learned in a weekend course makes us vulnerable to the questioning of our profession and of our skills as surgeons.''[12] This raises the issue of whether the surgeon should critically reflect on his/her own competence to perform a technique following such a short introduction, prior to using the technique on the first 'suitable' patient. The ethical boundaries of using patients as 'guinea pigs' in order to refine innovative surgical skills are indistinct and, in practice, remain largely a matter of personal professional conscience. In a prospective analysis of 1518 laparoscopic cholecystectomies, one US centre showed that the incidence of bile duct injury in the first 13 patients was 2.2% compared with 0.1% in subsequent patients indicating a higher morbidity at the steep end of the learning curve.[13] In the pioneering days of laparoscopic cholecystectomy, it was asserted that severe injury and even death were relatively common,[14] demonstrating the potentially detrimental impact upon patients when a new surgical procedure is introduced. A similar phenomenon was also observed in patients undergoing carotid angioplasty. The earliest group of patients in Lin's series incurred an 8% death/stroke rate which had declined to 0% over a 40 month period.[15] Notwithstanding the good intentions of anyone wishing to introduce a new intervention, purely from an ethical perspective, harm suffered by a patient at this early 'learning curve' stage cannot be in his/her best interest, despite the contention that the procedure is therapeutic. Such practices may compromise the patient's trust in the surgeon.[16]

Legal and Ethical Considerations

In the UK, the legal test for the required standard of care is based on the '*Bolam*' principle. This represents the standard of care that is endorsed by a responsible body of professional opinion. Any clinical care that falls below this standard could form the basis of a civil (or in extreme cases criminal) action. The *Bolam* principle is applied in circumstances where an action is brought in negligence.

In the context of novel treatments, difficulties may arise with ascertaining a 'responsible body of professional opinion'. By its very nature, a surgeon performing an innovative procedure may be at the frontier of medical science so that no other experts may be found to constitute a ''responsible body'' who are then able to assert an authoritative opinion. It is settled law that deviation from approved practice does not necessarily amount to negligence, and in *Simms*[17] it was recognised that it would be against the public interest to impede medical progress just because of the absence of a *Bolam* endorsement. It remains to be tested as to how the courts would assess the legal standard in a case of alleged negligence involving the use of an innovative surgical or interventional technique. Some factors that might be considered would be the extent to which its use was justified in the circumstances, whether there was evidence of previous trials of the treatment, the seriousness of the patient's condition and the extent of the foreseeable risk in the procedure.[18]

A concept traditionally used by medical researchers as a cognitive justification for entering patients into research trials is that of 'equipoise', a situation described as a clinician's 'honest doubt as to which of two clinical interventions is more beneficial for the patient'.[19] At the bedside, this mandates that a patient should not be randomly assigned to one of two or more different treatment options unless there is a state of honest, collective professional uncertainty as to which treatment is superior. In practice, the state of equipoise is there to show that random

assignment between two or more different procedures is therapeutically reasonable, and under these circumstances, it would not be unethical for a doctor to administer the new treatment.

At the commencement of a new treatment modality it is not possible for anyone, including the clinician, to know with certainty whether the anticipated benefits of the new technique will be superior to those currently available. At this stage true equipoise will exist. As experience is gained, however, this position is likely to change. Since it is apparent that the dividing line between innovation and research is finely balanced, the concept of equipoise can be extrapolated to the learning curve. This serves to add a further dimension of complexity to the ethical equation. As was identified in Bristol,[7] the expertise of each individual surgeon has a unique and measurable impact upon the likely success of an intervention. Accordingly, any surgeon on a learning curve (despite his pre-existing unquestionable expertise and experience) is likely to have a lower success rate at the start of a novel technique.

To what extent can it be ethically justifiable for an experienced surgeon, already highly proficient in a procedure, to embark upon a learning curve for an innovation, the benefits of which are still speculative, and in the knowledge that experience might be gained at the possible cost to early recipients of care? Early problems with any new technique may skew results and could have a higher morbidity and mortality, or expose the patient to more adverse events that conventional treatment. In the more traditional research setting when adverse events become apparent, the research is stopped. However, with innovative therapy there is no such constraint as this type of information is regarded as an essential precursor towards developing formal paradigms (such as randomised controlled trials) that are then used to build an evidence base.

Consider a situation where the use of an innovative procedure on twelve patients is a mandatory requirement before participation in a formal trial can take place. It is a moot point whether the procedure has to be undertaken in all of the twelve patients, or whether it should be pre-emptively terminated if the emergent distortion in the learning curve is indicative of recurring adverse events to participants. Whilst it is accepted that the shape of the learning curve will vary among individual surgeons and the specific task in hand,[20] nonetheless we propose that it should be an indicator of the proficiency and safety of an innovative technique. We do not support the claim that with any new surgical procedure a randomised trial should begin with the first patient,[21] as this could potentially stifle advancement in surgical technique. However, we do hold the firm conviction that the learning curve needs careful monitoring to ensure safety and efficacy.

The occurrence of harm to a patient on the learning curve of an innovative surgical technique might be a reason to stop the technique. However, the occurrence of harm in itself should not necessarily discourage the technique as this may be due to an array of confounding variables including the intrinsic abilities of the operator. Key factors to consider would be the seriousness of the harm and its frequency. A balance needs to be struck between compounding a problem of injury to patients and the somewhat tenuous utilitarian argument that individual morbidity is justified on the grounds of possible long-term wider good for future recipients of such interventions. The moral conscience of the individual surgeon engages forcefully at this critical juncture, especially as the surgeon is usually an experienced practitioner who is able to offer an alternative traditional technique with which he is familiar. In the absence of the belief that equipoise exists at this stage, the notion that the clinician should continue with the technique is repellent and would fly in the face of professionalism.

A Patient-Centred Focus for Innovative Intervention

The law has long since recognised the role of novel procedures in the development of medical science. In *Corbett*,[22] it was observed that an innovative procedure undertaken for genuine therapeutic reasons was a decision for the patient and doctor concerned in the case. This implies that the law should be kept out of decision-making. However, in recent years there has been a decline in professional autonomy, partly due to an increased regard for a patient's right to self-determination. This trend is reflected in the rise in litigation where insufficient information disclosure is alleged.[23]

Although consent is a legal defence in medical negligence claims, it is not conclusive. There is legal authority which holds that a patient cannot consent to negligent treatment. A medical practitioner can be liable for negligence based on inadequate information being given to the patient, as opposed to being negligent in the actual performance of the procedure.[24] Any defence for non-disclosure on the basis of therapeutic privilege would probably have little chance of success in the English courts. It is essential therefore that the patient is informed of any uncertainty regarding the risks, all reasonably foreseeable risks and an open discussion should be entered into regarding alternative established surgical procedures. Thus, the need for patient consent raises particular and unique complexities in the context of therapeutic innovation.

The Declaration of Helsinki requires that a patient is informed of all the risks and benefits inherent in an innovative procedure.[25] Case law mandates that the level of information disclosed regarding risk given to a patient during the consent process largely depends upon what is a material risk to that particular patient.[26] The relative inexperience of a surgeon embarking on a learning curve might seriously adversely impact upon the outcome. Arguably, this risk is material and therefore subject to disclosure in law. There may be an additional legal onus on the clinician to ensure that the patient understands all aspects of the procedure before it is attempted. However, the extent to which this is feasible in practice is dubious. The fact that the procedure has had limited application precludes the provision of critical information that a patient may expect including an individual surgeon's success rates. Performance data of a surgeon may be a material factor for a patient in the consent process. An honest portrayal of the *lack* of available information must be made clear.

In order to legitimise innovative care, consent based upon adequate information is mandatory. In a recent study of surgeons involved in new procedures, only one third

specifically mentioned the innovative nature of the anticipated operation during the consent process.[27] In the United States, much of the litigation involving novel surgical techniques have revolved around lack of adequate consent and not being informed that the technique was experimental in nature.[28] In Europe such practice could form the basis of a legal challenge founded on the violation of Human Rights. Lack of informed consent prior to innovative treatment could breach articles 3 and 8 of the European Convention on Human Rights. Autonomy, as protected by Article 8, could be violated through compromising self-determination as a result of inadequate information being provided. Furthermore, a recipient of novel treatment might allege a violation of article 3, which prohibits inhumane and degrading treatment, in the absence of full information disclosure. Surgeons should, therefore, be diligent in ensuring that patients are fully aware that the proposed procedure is innovative in nature, and that they understand that the clinician may be uncertain of outcome as well as being 'on a learning curve'. Failure to do so would be contrary to good medical practice and could lead to litigation.

Conclusion

History has shown that advancements in clinical care are an essential aspect of a modern health service and, as such, should be encouraged and facilitated. Surgical practice is a well regulated speciality, a position shared by clinical research. Innovation, however, sits in a perceptible lacuna, in that regulation exists largely at a personal, professional level. Whilst it is clear that regulation and control is necessary in order to prevent risk to patients, control cannot be imposed to such a degree that innovation is stultified and progress stopped. However, in the absence of a regulatory framework, there is a real danger that patients might be inadvertently harmed.

We would therefore propose that where the surgeon embarks on any learning curve, it is imperative that risks and outcomes in the procedure should be subjected to early dissemination in order to facilitate learning and the avoidance of recognised harm. Good medical practice requires the surgeon to inform the patient of any uncertainty regarding risks associated with the procedure, ensure that the patient fully understands that the procedure is new and that they have used the technique on few, if any, patients before. It is essential that the surgeon should never forget that they should be acting in their patients best interest at all times. It is therefore recommended that surgeons should always reflect on their own competence to perform any novel techniques in order to avoid unnecessary harm to patients Not to do so may be deemed as negligent practice in light of the criticism arising from the Bristol Report and the fact that autonomy and self determination is vehemently protected under domestic and European law.

References

1 American college of surgeons statement on emerging technologies and the evaluation of crudentials. *Am Coll Surg Bull* 1994; **79**:40—1.
2 Price D. Remodelling the regulation of postmodern innovation in medicine. *International Journal of Law in Context I*, 2:121—141.
3 Royal College of Physicians (1996, para. 6.4).
4 Price D. Remodelling the regulation of postmodern innovation in medicine. *International Journal of Law in Context I*, 2:130.
5 Price D. Remodelling the regulation of postmodern innovation in medicine. *International Journal of Law in Context I*, 2:134.
6 Scott LD. Innovative endoscopy — research or patient care? *J. Am Coll Surg* 2007;**102**:2617—9.
7 The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary. 1984—1995.
8 Price D. Remodelling the regulation of postmodern innovation in medicine. *International Journal of Law in Context I*, 2:123
9 British Medical Association Ethics Department. *Medical Ethics Today*. 2nd ed. BMJ Publishing Group; 2004. p. 496.
10 British Medical Association Ethics Department. *Medical Ethics Today*. 2nd ed. BMJ Publishing Group; 2004. p. 497.
11 Margo CE. When is surgery research? Toward an operational definition of human research. *J Med Ethics* 2001;**27**:40—3.
12 Rock JA, Warshaw JR. The history and future of operative laparoscopy. *Am J Obstet Gynaecol* 1994;**170**:7—11.
13 The Southern Surgeons Club. A prospective analysis of 1518 laparoscopic cholecystectomies. *N Engl J Med* 1991;**324**:1073—8.
14 Dent TL. Training, credentialing and granting clinical privileges for laparoscopic general surgery. *Am J Surg* 1991;**161**:399—403.
15 Lin PH, Bush RL, Peden E, Zhou W, Kougias P, Henao E, et al. What is the learning curve for carotid artery stenting with neuroprotection? Analysis of 200 consecutive cases at an academic institution. *Perspect Vasc Surg Endovasc Ther* 2005;**17**:113—23.
16 Michel LA, Johnson P. Is surgical mystiques a myth and double standard in reality? 2002;28:66—70.
17 Simms v Simms [2003] 1 All ER 669.
18 Mason JK, McCall RA. Law and Medical Ethics. London Butterworths. p. 218—229.
19 Liddell K, Bion J, Chamberlain D, Drumi C, Kompanje E, Lemaire F, et al. Medical research involving incapacitated adults: implications of the EU clinical trials directive 2001/20/EC. *Med L Rev*; 2006:384.
20 Soot SJ, Eshraghi N, Farahmand M, Sheppard BC, Deveney CW. Transition from open laparoscopic fundoplication: the learning curve. *Arch Surg* 1999;**134**:278—81.
21 Chalmers TC. Randomisation of the first patient. *Med Clin North Am* 1975;**59**:1035—8.
22 Corbett v Corbett [1971] 83,para99.
23 Chester v Afshar [2004] 3 WLR 927.
24 Sidaway v Board of Governors of the Bethlehem hospital and the Maudsley hospital [1984] AC 871.
25 Helsinki Declaration 6th version (2000).
26 Sidaway v Board of Governors of the Bethlehem hospital and the Maudsley hospital [1984] AC 871: Pearce v United Bristol Healthcare NHS Trust (1999) 48, CA BMLR 118.
27 Reitsma AM, Moreno JD. Ethical regulations in innovative surgery: the last frontier? *J Am Coll Surg* 2002;**194**:792—801.
28 Karp v Cooley, Anderson v George H Lanier Memorial Hospital (1974) 493 F 2d 408 (US CA, 5th Cir): Estrada v Jaques 321 S.E. 2d 240 (N.C. Ct App 1984).